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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,624	01/22/2002	Sean H. Adams	09800081-0066	4963

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,624

Applicant(s)

ADAMS ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29 and 32-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29 and 32-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 27-29, 32-39 are pending.

Applicant's amendment of claims 27-29, cancellation of claims 1-26, 30-31, and addition of claims 32-39 in a communication filed on 2/15/2005 is acknowledged.

Claims 27-29, 32-39 are directed in part to non-elected subject matter, i.e. methods of screening which require measuring expression of polynucleotides encoding the polypeptides of SEQ ID NO: 4 and SEQ ID NO: 6. In view of the fact that SEQ ID NO: 4 comprises all of SEQ ID NO: 2 except for the last 13 amino acids, the previously conducted search is deemed co-extensive in regard to a method of screening which requires measuring expression of a polynucleotide encoding the polypeptide of SEQ ID NO: 4. Thus, the restriction requirement between Group XXV and XXVI previously applied is hereby withdrawn. However, SEQ ID NO: 6 is not a fragment of either SEQ ID NO: 2 or 4, therefore an additional search would be required since the previously conducted search is not deemed co-extensive in regard to a method as claimed wherein the polynucleotide encodes the polypeptide of SEQ ID NO: 6. Claims 27-29 and 32-39, as directed to a method of screening which requires measuring expression of polynucleotides encoding the polypeptides of SEQ ID NO: 2 or 4, are under consideration and are being examined herein. Non-elected subject matter will not be examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claims 27-29, 32-34, 36-39 are objected to since they are directed in part to non-elected inventions, i.e. methods of screening a patient by measuring the expression of polynucleotides encoding the polypeptide of SEQ ID NO: 6. For examination purposes no patentable weight will be given to the terms "SEQ ID NO: 6" or "SEQ ID NO: 5". Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. New claims 32-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility. This rejection as it relates to claims 32-39 is necessitated by amendment.
4. Applicants argue that the data presented in the specification shows that BFIT is strongly induced in the brown adipose tissue of mice exposed to cold and that obesity resistant mice fed a high fat diet revealed a 2-fold higher expression of BFIT as compared to obesity prone mice. Also, Applicants submit that BFIT in nonobese mice was 2.5-fold higher compared to obese mice and that BFIT expression in food-restricted mice was enhanced to the same levels in cold challenged mice. Therefore, Applicants submit that the data supports the asserted utility for the claimed method.
5. Applicants arguments have been fully considered. While the arguments are deemed persuasive in regard to a method of screening a patient for predisposition to obesity wherein the expression of a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or 4 is measured, and wherein decreased expression as compared to a control sample indicates predisposition to obesity (claims 27-29), Applicant's arguments are not deemed persuasive in regard to a method of screening a patient for monitoring metabolism, a method for detecting an increase in metabolism, or a method for detecting a decrease in metabolism in a patient, as encompassed by claims 32-39. Applicant's data in mouse models and the teachings of the prior art as indicated in Example 4 of the specification appear to suggest linkages between expression of the human homolog (encodes the polypeptide of SEQ ID NO: 2 and its splice variant of SEQ ID NO: 4), of the mouse BFIT gene and obesity predisposition, particularly in view of Applicant's disclosure of the chromosomal location of the human BFIT gene and that of markers

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presumed to be involved in body fat/insulin levels suggested by the prior art. However, neither the prior art nor the specification provide any teaching in regard to a linkage between expression of the recited polynucleotides and increased or decreased metabolism. While one could argue that obesity is related to the term "metabolism" in that certain disorders in metabolism would lead to obesity, there is no teaching or suggestion in the specification or the art which indicates that (1) predisposition to obesity always correlates with lower metabolism so that one could extrapolate lower expression of the polynucleotides of SEQ ID NO: 1 or 3 to lower metabolism, or (2) decreased expression of the polynucleotides of SEQ ID NO: 1 or 3 directly correlate with decreased metabolism. Thus, Applicant's asserted utility for the claimed method, particularly in view of a lack of knowledge as to a correlation between expression of the BFIT gene taught in the specification and increase/decrease in metabolism, constitutes a utility which requires further research to identify or reasonably confirm a "real world" context of use. As such, the asserted utility is not considered substantial and the method of claims 32-39 does not meet the utility requirements under 35 USC 101.

6. Claims 32-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Even if a specific and substantial or well established utility is found for the method of claims 32-39, the following rejection applies. Claims 27-29, 32, 36-39 are rejected under 35 U.S.C. 112, first

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paragraph, because the specification, while being enabling for a method of screening a patient for predisposition to obesity wherein said method comprises measuring the expression of a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or 4, does not reasonably provide enablement for (a) a method of screening a patient for predisposition to obesity wherein said method comprises measuring the expression of a polynucleotide encoding a BFIT polypeptide having thioesterase activity and comprising at least 92% sequence identity to the polypeptide of SEQ ID NO: 2 or 4, or (b) a method of screening a patient for increased or decreased metabolism by measuring the expression of (i) a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or 4, or (ii) a polynucleotide encoding a polypeptide having thioesterase activity and comprising at least 92% sequence identity to the polypeptide of SEQ ID NO: 2 or 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This rejection is necessitated by amendment.

9. Applicants argue that the claims as amended are similar to what was indicated as enabled by the specification. Applicants submit that (1) human BFIT1 and human BFIT2 have about 92% sequence identity, (2) working examples of how to detect expression of polynucleotides encoding BFIT1 and BFIT2 have been presented, and (3) several models of how decreased expression of BFIT polynucleotides is associated with obesity.

10. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of amended claims 27-29 or avoid the rejection of new claims 32-39. While it is agreed that there is at least 92% sequence identity between the polypeptide of SEQ ID NO: 2 and 4 (SEQ ID NO: 4 is an splice variant of SEQ ID NO: 2 which comprises amino acids 1-594 of SEQ ID NO: 2), the claims as written do not only encompass SEQ ID NO: 2 and 4 but any polypeptide having at least 92% sequence identity to SEQ ID NO: 2 or 4 also having thioesterase activity. While the specification teaches that there is a linkage between expression of a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or

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4 and obesity, neither the specification nor the art teach a linkage between expression of a polynucleotide encoding a thioesterase polypeptide having at least 92% sequence identity to the polypeptide of SEQ ID NO: 2 or 4 and obesity. Furthermore, the specification is silent in regard to the structural elements in the polypeptide of SEQ ID NO: 2 or 4 which are required in any 92% structural homolog of the polypeptide of SEQ ID NO: 2 or 4 such that they can be markers for predisposition to obesity or increased/decreased metabolism. In addition, as indicated above in regard to new claims 32-39, the specification fails to provide any teaching or suggestion in regard to a linkage between expression of polynucleotides encoding the polypeptides of SEQ ID NO: 2 or 4 and increased or decreased metabolism, nor there is any indication that predisposition to obesity will directly correlate with lower metabolism so that one could extrapolate predisposition to obesity to lower metabolism. Therefore, for the reasons set forth above and those of record, one cannot reasonably conclude that the claimed invention is fully enabled by the teachings of the specification.

Allowable Subject Matter

11. Claims 27-29 would be allowable if limited to polynucleotides encoding the polypeptides of SEQ ID NO: 2 or 4.

Conclusion

12. No claim is in condition for allowance.

13. Applicant's amendment of claims 27-29 and addition of claims 32-39 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 3, 2005


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